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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,410	07/10/2001	Dan E. Robertson	DIVER1180-2	8980

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/12/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/903,410

Applicant(s)
Robertson et al.

Examiner
Rebecca Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 2, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 40-55, 61-63, 65, 67-85, and 88-102 is/are pending in the application.
- 4a) Of the above, claim(s) 42-55, 61-63, 65, and 88-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-21, 23, 40, 41, 67-85, and 93-102 is/are rejected.
- 7) ☒ Claim(s) 2 and 22 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 6) ☐ Other:

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Claims 24-39, 56-60, 64, 66, 86, and 87 have been canceled. Claims 1-23, 40-55, 61-63, 65, 67-85, and 88-102 are at issue and are present for examination.

Applicant's election with traverse of Group I(D) in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the invention of Group I(G) should be rejoined as the coexamination of Groups I(D) and I(G) would not be an undue burden. This is not found persuasive because the two esterases are substantially structurally distinct such that search of the esterase of Group I(D) will not necessarily lead to art applicable to the esterase of Group I(G) and vice versa. As such the search of the additional structure would constitute an undue burden.

Applicants further request rejoinder of the method claims of Claims 42-55, 61-63, 65 and 88-92 which recite methods of use of the polynucleotides of Group I. However, as the corresponding product claims are not currently allowable, rejoinder is not currently required. The applicability of rejoinder will be evaluated upon allowance of the product claims of the elected group.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 42-55, 61-63, 65 and 88-92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

The papers filed under 37 CFR 1.48(a) are deficient because:

It lacks a request to correct the inventorship that sets forth the desired inventorship change and the required fee under 37 CFR 1.17(i).

Claims 1-23, 40-41, 67-85, and 93-102 are objected to as including non-elected subject matter. Applicant should note that for purposes of examination the claims have been examined as if drawn to the elected subject matter only.

Claims 3-5, 67-84, 97 and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-5 and 67-84 are indefinite in the recitation of "high stringency" or "highly stringent conditions", "moderate stringency" or "moderately stringent conditions" or "low stringency" as the specification does not define what conditions constitute high, moderate and/or low stringency. While pages 11 and 38-40 of the specification describe a variety of conditions

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which are intended to be high, moderate and/or low stringency, there is nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered high, moderate and/or low stringency varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a gene of SEQ ID NO:26, a sequence must be to be included within the scope of these claims.

Claims 67 (upon which claims 68-81 depend), and 82-84 are indefinite in the recitation of "from about 10 to 50 nucleotides in length or at least about 10, 15, 20, 25, 30, 35, 40, 45, 50, 75, 100, 150, or 200 nucleotides in length" as it makes the lengths of the recited oligonucleotide encompassed vague and confusing". Furthermore Claims 82-84 are further confusing in reciting lengths of less than 15 bases but also requiring an area of at least 15 contiguous nucleotides having specific features. For purposes of examination this entire recitation is interpreted as "at least 10 nucleotides" in Claims 67-81 and "at least 15 nucleotides" in Claims 82-84.

Claims 69-78 are indefinite in the recitation of "% sequence identity to the nucleic acid" as it is unclear what nucleic acid is being referenced. For purposes of examination it is presumed

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that "% sequence identity to the nucleic acid of claim 1 or its complementary sequence" was intended.

Claims 67-84 are unclear in whether the % sequence identity recited is to the full length of a polynucleotide of claim 1 or to only a corresponding portion thereof. For purposes of examination it is assumed that the identity is only to the corresponding portion of a polynucleotide of claim 1.

Claim 97 is confusing in the recitation of "nucleic acid at least about...". It is assumed that "nucleic acid comprising at least about..." was intended.

Claim 99 is confusing in the recitation of "vector of claim 98 comprising a wherein the vector". It is assumed that "vector of claim 98, wherein the vector" was intended. Furthermore the inclusion of "a phase" and "a fosmid" in the recited Markush groups is not understood as these are not known types of vectors.

Claims 1, 3-21, 23, 40, 41, 67-85 and 93-102 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3-21, 23, 40, 41, 67-85 and 93-102 are directed to polynucleotides having at least 50% sequence identity to SEQ ID

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NO:26 and encoding a polypeptide with an esterase activity (Claims 1 and 15), or fragments and variants thereof (Claims 3-14, 67-84, and 97), polynucleotides comprising at least 10 bases of a sequence having 70% identity to SEQ ID NO:26 and encoding a polypeptide having esterase activity (Claim 16) or fragments and variants thereof (Claims 17-21 and 93-96), or polynucleotides comprising fragments of SEQ ID NO:26 (Claim 85) or encoding fragments of SEQ ID NO:36 (Claim 23) or vectors and host cells comprising said nucleic acids (Claims 98-102) or methods of expressing said nucleic acids (Claims 40 and 41). Claims 1, 3-21, 23, 40, 41, 67-85 and 93-102 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polynucleotides and variants and fragments thereof that have not been disclosed in the specification. No description has been provided of the structure and function of the modified polynucleotide sequences encompassed by the claims. No information, beyond the characterization of SEQ ID NO:26 which encodes the esterase of SEQ ID NO:36 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polynucleotides. The specification does not contain any disclosure of the structure and function of all the polynucleotide sequences derived from SEQ ID NO:26, including fragments and variants within the scope of the claimed

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genera. The genera of polynucleotides claimed is a large variable genus including peptides which can have a wide variety of functions and with the potentiality of generating many different antibodies. It should be noted that even within Claim 1 which is limited to polynucleotides encoding polypeptides with esterase activity there are a wide variety of functions encompassed as "esterase activity" encompasses an enormous number of distinctly different functional activities. Ester bonds are present in an enormous number of different chemical compounds and enzymes which will cleave one type of ester bond will not cleave all ester bonds. Therefore many structurally and functionally unrelated polynucleotides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

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Claims 1, 3-21, 23, 40, 41, 67-85 and 93-102 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding SEQ ID NO:36, does not reasonably provide enablement for any polynucleotide having at least 50% sequence identity to SEQ ID NO:26 and encoding a polypeptide with an esterase activity or any polynucleotide comprising at least 10 bases of a sequence having 70% identity to SEQ ID NO:26 and encoding a polypeptide having esterase activity, or any polynucleotide comprising a fragment of SEQ ID NO:26 or encoding fragments of SEQ ID NO:36, or all fragments and variants thereof or vectors and host cells comprising said nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1, 3-21, 23, 40, 41, 67-85 and 93-102 are directed to polynucleotides having at least 50% sequence identity to SEQ ID NO:26 and encoding a polypeptide with an esterase activity (Claims 1 and 15), or fragments and variants thereof (Claims 3-14, 67-84, and 97), polynucleotides comprising at least 10 bases of a sequence having 70% identity to SEQ ID NO:26 and encoding a polypeptide having esterase activity (Claim 16) or fragments and variants thereof (Claims 17-21 and 93-96), or polynucleotides

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comprising fragments of SEQ ID NO:26 (Claim 85) or encoding fragments of SEQ ID NO:36 (Claim 23) or vectors and host cells comprising said nucleic acids (Claims 98-102) or methods of expressing said nucleic acids (Claims 40 and 41). The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides encoding esterases and variants and fragments thereof broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the polynucleotide of SEQ ID NO:26 which encodes the esterase of SEQ ID NOS 36.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of

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success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass an enormous number of polynucleotide fragments and variants of the polynucleotide of SEQ ID NO:26 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting esterase activity; (B) the general tolerance of esterases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including an enormous number of

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polynucleotide fragments and variants of the polynucleotide of SEQ ID NO:26. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-21, 67-79, 82-85, and 93-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (GenBank Accession No. S72930) or Taylor et al. (GenBank Accession No. X00520).

Wong et al. teach a nucleic acid sequence comprising a region (nucleotides 655-671 of Wong et al.) identical to bases 351-368 of SEQ ID NO:26. As such Wong et al. anticipate all of the instant claims.

Taylor et al. teach a nucleic acid sequence comprising a region (nucleotides 304-320 of Taylor et al.) identical to the

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complement of bases 536-552 of SEQ ID NO:26. As such Taylor et al. anticipate all of the instant claims.

Claims 1, 3-15, 23, 40, 41, 67-84, and 98-102 rejected under 35 U.S.C. 102(b) as being anticipated by Robertson et al. (WO 97/30160).

Robertson et al. teach the gene of SEQ ID NO:26, fragments thereof useful as probes, vectors and host cells comprising this gene and expression of this gene. Thus Robertson et al. anticipates all of the instant claims. It is noted that Robertson et al. was published after the filing date of grandparent application 08/602,359. However the grandparent application does not provide support for the instant claims. The recitation of a genus of nucleic acids having 50% identity to SEQ ID NO:26 and encoding an esterase protein in claim 1 (upon which Claims 3-15, 40, 41, 67-84 and 98-102 depend) is not described in the prior application. Similarly the recitation of a genus of nucleic acids encoding a polypeptide comprising at least 10 amino acids of SEQ ID NO:36 in Claims 23 is not described in the prior application. As such the instant claims have not been granted the benefit of the filing date of the grandparent application and Robertson et al. anticipates the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca

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Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Rebecca Prouty", with a stylized flourish at the end.

Rebecca Prouty
Primary Examiner
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